EXHIBIT 2

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419 Dkt. No 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO:	)	
All Cases	)	

AFFIDAVIT OF C.J. GIDEON, Jr.

[FILED IN SUPPORT OF TENNESSEE CLINIC DEFENDANTS' RESPONSE TO MOTION OF THE UNITED STATES FOR A STAY OF CERTAIN DEPOSITIONS PENDING RESOLUTION OF RELATED CRIMINAL PROCEEDINGS]

STATE OF TENNESSEE)
)
COUNTY OF DAVIDSON)

Introduction and Background

1. I am C.J. Gideon, Jr. I am over the age of 18 and competent to execute this affidavit. The affidavit is based on my experience and personal knowledge.

2. I am lead counsel for the Tennessee Clinic Defendants in the 100+ lawsuits filed against them arising from the 2012 fungal meningitis outbreak.

3. The Tennessee Clinic Defendants are divided into three groups, each with lawsuits pending against them:

a. The STOPNC Defendants: The STOPNC Defendants (all located in Nashville, Tennessee) include Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, A Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; and Vaughan Allen, MD. There are cases brought by 117 patients.

b. The SSC Defendants: The SSC Defendants (located in Crossville, Tennessee) include Specialty Surgery Center, PLLC; Kenneth R. Lister, MD; and Kenneth Lister, MD, PC. There are lawsuits brought by 24 patients.

c. Dr. Jones: Donald Jones, MD (located in Oak Ridge, Tennessee) is a defendant in cases brought by two patients.

4. I graduated from Duke University in 1975. I obtained my law degree from Vanderbilt University in 1978. Since that time, I have been a practicing trial lawyer in Nashville, Tennessee, trying cases in Alabama, Kansas, Kentucky, Texas, and Tennessee. The majority of my practice is spent on representing health care providers in professional negligence cases. Since graduation from law school, I have tried roughly 200 cases to verdict, most in the defense of hospitals, clinics, physicians, and other health care providers alleged to have committed some form of professional negligence. I have handled scores of other health care-related cases and also litigated dozens of cases on behalf of injured persons, including through trial.

5. Based upon my experience and personal involvement in this MDL, I am competent to testify to the prejudice that my clients will suffer – particularly the negative impact on the defense of the cases against them – if we are forced to conduct expert discovery and try the first civil case prior to having the opportunity to depose and preserve the testimony of employees of NECC and MSM.

6. In the telephone "meet and confer" discussions with Assistant United States Attorney Amanda Strachan, and Assistant United States Attorney George Varghese, they have repeated that, even if we depose multiple former employees of NECC and MSM, we will *never* uncover the same volume or quality of information we would receive by attending the criminal trial, set to begin on April 4, 2016. While it is impossible to compare or verify the results of events that have not yet occurred, the representations by counsel for the United States cannot be rebutted. Crediting those statements as informed and factual, it is clearly in our clients' interest, and in the interest of every party that wants an ultimate civil verdict to be based on the truth, to stay the civil process (expert discovery and any civil trial) until the April 4, 2016, criminal trial is concluded.

Summary of Tennessee Clinic Defendants' Position on Government's Motion to Stay

7. As explained in the contemporaneously-filed *Response to Motion of the United States for a Stay of Certain Depositions pending Resolution of Related Criminal Proceedings*, we do not oppose a stay of the depositions of NECC and MSM employees *if* we are *not* compelled to engage in common expert discovery and conduct the first civil trial prior to taking the depositions of the NECC and MSM personnel. Thus, we do not oppose a stay of these depositions until the criminal trial is over, provided the Court (1) also stays the common expert disclosure deadlines and (2) the initial civil trial is set so as to permit us to secure and utilize the essential discovery from NECC and MSM prior to the civil trial.

8. A stay of the NECC/MSM depositions will not halt progression of the civil cases. We will continue with non-NECC/MSM discovery,[1] and prepare the submission of the record and briefs to the Tennessee Supreme Court on material questions of Tennessee law.[2] Following the criminal trial and termination of the stay on the NECC/MSM discovery in the civil cases, we would take the depositions of the NECC/MSM employees,[3] move into common expert discovery, and complete the common proceedings in the MDL.

9. For the reasons discussed in this affidavit and in the *Response to Motion of the United States for a Stay of Certain Depositions pending Resolution of Related Criminal Proceedings*, if we are required to proceed to common expert discovery, followed in the near term by the first civil trial or series of civil trials, we must oppose the Motion to Stay of the United States. We require the NECC/MSM depositions to adequately defend our clients.

[1] For example, the deposition of the SSC management company is set for September 28 and 29. Following that, there will likely be motion practice regarding addition of the management company to the lawsuits. Additionally, there is at least one remaining witness for the Saint Thomas Entities who can be deposed. There may also be some case-specific fact discovery that can be conducted while the stay is in place. There are thousands of documents that have been produced that, given the compressed discovery schedule, still require internal review. There are outstanding document discovery issues yet to be decided. Simply, there is work to do on the cases apart from the NECC/MSM discovery.

[2] *See* Order, Honorable Joe Brown, United States Magistrate Judge, in M.D. Tenn., No. 2:15-cv-00026, Dkt. 77 (9/23/15) (ordering parties in SSC declaratory judgment action to brief issue of viability of product liability claim against health care provider for certification to Tennessee Supreme Court).

[3] We would also take the depositions of the FDA and some or all of the criminal defendants, which were stayed pending the criminal trial.

Law in Tennessee on Comparative Fault

10. In 1992, The Tennessee Supreme Court revamped tort law, discarding contributory negligence in favor of the doctrine of modified comparative fault.[4] In Health Care Liability claims, the health care provider may assert, as an affirmative defense to the claim, that a non-party was at fault for the injury.[5] This affirmative defense is available even if the potentially at-fault individual or entity is immune.[6] Tennessee's Supreme Court has found that the jury should be allowed to allocate fault to any party or non-party proven to be responsible for the plaintiff's injury, in the percentages the jury deems appropriate.[7] The fundamental theme repeatedly endorsed by the Tennessee Supreme Court is that liability should be allocated consistent with the actual fault of the parties and non-parties, and that defendants should not shoulder a higher degree of liability than the case-specific facts warrant.[8]

11. It is the defendant's burden to offer evidence establishing the affirmative defense of non-party comparative fault, *i.e.*, that the non-party acted negligently and caused injury (was at fault).[9]

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[4] *See McIntyre v. Balentine*, 833 S.W.2d 52, 57-58 (Tenn. 1992).
[5] *See Carroll v. Whitney*, 29 S.W.3d 14, 18-19 (Tenn. 2000).
[6] *See Carroll*, 29 S.W.3d at 19 ("we hold that when a defendant raises the nonparty defense in a negligence action, a jury may generally apportion fault to immune nonparties").
[7] *See Hall v. Derrick*, No. W2003-01353-COA-R3-CV, 2004 WL 2191016, *4 (Tenn. Ct. App. 2004) (noting that, once it is determined two parties were negligent, the trier of fact must allocate the percentage of fault) (cites omitted).
[8] *Carroll*, 29 S.W.3d at 20-21 ("our decision is also grounded in the rationale that led to the adoption of comparative fault in the first place: fairness to the parties by linking fault with liability"; "we rejected contributory negligence and joint and several liability in favor of comparative negligence to achieve a fairer and tighter fit between fault and liability[, which is] lost...when some participants to an act of negligence are excluded from the apportionment of fault"; "the exclusion of some tortfeasors from the universe of persons and entities to whom fault can be allocated has the effect of reviving joint and several liability"; "[w]hen a tortfeasor is insolvent, either a plaintiff will receive less than full compensation, or a solvent defendant will be liable for an amount greater than his proportional fault....[T]his Court declined to adopt [a rule that reallocated liability to the solvent tortfeasors]"; "out of fairness to defendants, we allowed the burden of a judgment-proof insolvent tortfeasor to fall on the plaintiff").
[9] *Carroll*, 29 S.W.3d at 21 ("defendants are not permitted to shrug off blame with a casual 'I didn't do it; she did.' Rather, because the nonparty defense is an affirmative defense, a jury can apportion fault to a

12. Specific to the fungal meningitis litigation, Tennessee law allows the affirmative defense that NECC, its affiliates, and its employees (and any other non-party, even if immune or already settled) acted wrongfully and caused or contributed to cause injury to the plaintiffs in this litigation.

13. We will bear the burden at trial to put on proof establishing that NECC and its affiliates (or any other non-party) were at fault. This will require us proving to the jury that NECC and its affiliates (1) acted wrongfully and (2) caused or contributed to cause injury to the Plaintiff.

14. If we prove that NECC and its affiliates were at fault, the jury will be instructed to allocate whatever portion of fault it deems appropriate to NECC and its affiliates, and that percentage will necessarily lower the percentage of fault that may be attributed to our clients.[10]

Litigation Strategy – Comparative Fault

15. Our Nashville clients were first sued in Tennessee state court in early-2013, in a handful of cases, including *Wayne A. Reed, individually and as Husband and next of kin of decedent, Diana Reed, v. Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; Saint Thomas Network; Saint Thomas Health; and St. Thomas Hospital*, Davidson County Circuit Court, No. 13C417, filed on January 29, 2013.

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nonparty only after it is convinced that the defendant's burden of establishing that a nonparty caused or contributed to the plaintiff's injury has been met") (citing *Estate of Hunter v. Gen. Motors Corp.*, 729 So.2d 1264, 1273 (Miss. 1999) ("It would be patently unfair in many cases to require a defendant to be 'dragged into court' for the malfeasance of another and to thereupon forbid the defendant from establishing that fault should properly lie elsewhere")).

[10] For example, if the jury finds that both the Tennessee Clinic Defendants and NECC acted wrongfully and caused the Plaintiff's injury in a case, the jury will be instructed to allocate 100% of the fault between the two (*e.g.*, 50/50, 90/10, 70/30, 20/80, *etc.*). *See, e.g.*, *Grandstaff v. Hawks*, 36 S.W.3d 482, 486 (Tenn. Ct. App. 2000) ("[t]he jury returned a verdict assessing each party's damages and allocating the parties' fault as follows: 49% to Mr. Hawks, 49% to Mr. Forrest, and 2% to Ms. Grandstaff").

16. Assertion of comparative fault against NECC and its affiliates was not an 11th hour consideration. We have asserted the comparative fault of NECC and its affiliates (plus additional non-parties) as an affirmative defense from the outset of this litigation. In our state court answer to the *Reed* lawsuit, filed on March 1, 2013, over two-and-a-half years ago,[11] beginning at page 27 and concluding at page 55, we asserted the comparative fault of multiple non-parties, including NECC, Barry Cadden, Lisa Cadden, Doug Conigliaro, Carla Conigliaro, Glenn Chin, the FDA, the Massachusetts Board of Pharmacy, Medical Sales Management, John Notarianni, Mario Giamei, Analytical Research Laboratories, Inc., and UniFirst.

17. Consistent with this litigation strategy, we negotiated at length with the Trustee for language in the Bankruptcy Plan that specifically reserves our right to assert comparative fault against the settling parties (*e.g.*, NECC and MSM).[12]

18. Our litigation strategy has not changed since 2013. We have consistently, throughout this litigation, made efforts at written and oral discovery of NECC, its affiliates, and their employees, and of other non-parties, to develop proof to support the comparative fault defenses.

[11] Attached as Exhibit 1 to this affidavit.
[12] *See* Dkt. 1289-1 of bankruptcy docket (No. 12-19882).

19. Specifically, as outlined in the *Response to Motion of the United States for a Stay of Certain Depositions pending Resolution of Related Criminal Proceedings*, we (either on our own or in conjunction with our co-defendants, the Saint Thomas Entities) have attempted the following formal and informal discovery to assist in developing the comparative fault defenses:

a. FOIA requests to the FDA

b. Public information requests to the Massachusetts Board of Pharmacy

c. Numerous attempts to interview former NECC and MSM employees

d. Written discovery to the PSC, seeking documents related to the fault of NECC and other non-parties[13]

e. Written discovery to the NECC insiders[14]

f. Written discovery to NECC[15]

g. Written discovery to NECC's affiliated companies (*e.g.*, MSM, GDC)[16]

h. Written discovery to tortfeasors not affiliated with NECC (*e.g.*, ARL, UniFirst, Liberty)[17]

i. Subpoena and 30(b)(6) notice to the FDA[18]

j. Subpoenas and 30(b)(6) notice to the Massachusetts Board of Pharmacy[19]

k. 30(b)(6) notice to NECC[20]

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[13] *See* Dkt. 1830.
[14] *See, e.g.*, Dkt. 2195, 2196.
[15] *See* Dkt. 1813; *see also Motion to Compel Compliance to NECC*, dkt. 2190, 2191
[16] *See, e.g.*, Dkt. 1772.
[17] *See, e.g.*, Dkt. 1832.
[18] *See* Dkt. 1775, 1775-2.
[19] *See* Dkt. 1735.
[20] *See* Dkt. 1782-1.

l. Depositions of alleged non-party tortfeasors like ARL, UniFirst, and Liberty[21]

m. Notices of deposition and subpoenas for the NECC insiders and multiple NECC/MSM employees (*e.g.*, Barry Cadden, Doug Conigliaro, Glenn Chin, John Notarianni, Mario Giamei, Owen Finnegan, Joseph Connolly).[22]

20. Our discovery to support the comparative fault claims – as explained in the *Response* – has met a nearly universal brick wall. At this point, we have not – either by virtue of an order of the Court or pending motion – taken the deposition of *any* NECC or MSM employee. Basic NECC documents, such as personnel files and cleaning records, have not been produced.[23] It is a fair approximation to conclude that we have access to less than ten percent (10%) of the documents that have been produced in the criminal case, despite being tasked with proving the same wrongful conduct that the federal prosecutors intend to prove.[24]

21. Consistent with our litigation strategy, we have retained experts focused on reviewing the actions of NECC, its affiliates, ARL, Liberty, and UniFirst, with the expectation that they will testify at trial critical of these non-parties. The information learned in the depositions, combined with the expert testimony, will assist in proving the comparative fault of these non-parties.

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[21] *See, e.g.*, Notice at Dkt. 1884.
[22] *See, e.g.*, Notice at Dkt. 1782-4.
[23] *See Motion to Compel Compliance to NECC*, dkt. 2190, 2191.
[24] Admittedly, we only have to prove the negligence of NECC (and any other non-party) by a preponderance of the evidence. But, generally, both the Tennessee Clinic Defendants and the Government sit in the same position, both needing to affirmatively prove that NECC acted wrongfully and caused injury.

Depositions of Former NECC and MSM Employees

22. Currently the depositions of approximately a half-dozen NECC and MSM employees are set. These depositions are the subject of the Government's Motion to Stay.

23. We intend to take these depositions to (1) build a working knowledge of how NECC/MSM operated, (2) authenticate and explain documents produced in the litigation, (3) obtain testimony to share with our experts (*e.g.*, critical testimony about how and where the medication was made), (4) obtain testimony preserved for trial to support the allegations of comparative fault against NECC and its affiliates, (5) obtain testimony to use at trial to support the allegations of comparative fault against other non-parties (*e.g.*, ARL, UniFirst, the FDA), and (6) obtain testimony to support other non-affirmative defenses at trial (*e.g.*, to support our argument that the standard of care did not require the due diligence that the PSC contends was required).

24. Based on conversations with these witnesses and/or their lawyers, we believe that at least one former NECC/MSM employee, and maybe more, will provide substantive answers to questioning instead of pleading the Fifth to all questions asked. Thus, we do believe that the depositions will yield useful, substantive information to assist in our defense of the cases.

25. Even if the witnesses plead the Fifth, we maintain that they will be required to answer certain factual questions that will not reasonably implicate them.[25] For questions where the witness properly invokes the Fifth Amendment privilege, we

[25] *See U.S. v. Lileikis*, 899 F. Supp. 802, 804 (D. Mass. 1995).

maintain that we are entitled to an adverse inference instruction.[26] Thus, even if some witnesses plead the Fifth, the depositions still have value at trial for our clients.

Documents Obtained To-Date

26. It would be very, very difficult to convincingly prove the fault of NECC and its affiliates with the documents obtained to-date and with*out* testimony of any witnesses.

27. First, the documents that we have obtained to-date – in the absence of witness testimony from NECC and MSM – are simply that – unauthenticated, unexplained documents. We cannot prove the fault of NECC and its affiliates by standing up, handing a notebook of documents to the jury, attempting to tell the jury what they mean,[27] and sitting down. No competent trial lawyer would make that form of evidentiary presentation the basis for proving comparative fault against NECC; and, we expect that no judge would allow the introduction of evidence in that manner. Without witness testimony, the documents are of little use.

28. Second, as explained in the *Motion to Compel Compliance with Subpoena to NECC,*[28] we still do not have a complete set of relevant NECC documents. The PSC and Trustee continue to repeat the same self-serving mantra that we do not need any more documents, let alone the documents already in their possession, and that we surely should not need any witness testimony to prove the fault of NECC.[29] The

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[26] *See Lileikis*, 899 F. Supp. at 804 (citing general law on adverse inference).

[27] As an example, the documents which purport to describe the formulation, compounding, and sterilization of the three (3) bad batches of methylprednisolone acetate are difficult to interpret without a working knowledge of NECC's compounding practices. *E.g.,* NECC_MDL000005167. (These documents have been designated confidential by the Trustee. Copies will be provided to the Court if the Court would like to see them). To be meaningful to thoughtful, engaged jurors, these central but technical documents must be explained by a person with knowledge.

[28] Dkt. 2190, 2191.

[29] Hr'g Tr. p. 37-38 (Sept. 9, 2015 status conference).

interests of the PSC are clearly served by the most anemic proof of the comparative fault of NECC. The Trustee and his team of lawyers claim that nothing should be required of NECC because doing so would add to the $10,000,000.00 in aggregate fees they already seek from the tort trust common coffers. No reasonable trial lawyer would forego seeking clearly relevant documents because adverse parties repeat and repeat, "You have enough."[30]

29. Third, based on my experience (and that of every trial lawyer I have ever worked with in presenting a case), it is ineffective to present an affirmative case of fault without taking the depositions of and presenting trial testimony from actors of the at-fault party or non-party. It would be extremely difficult to try a case as a plaintiff and have to prove the case to a jury without taking the deposition of the defendant. Likewise, it would be extremely difficult trying a comparative fault allegation without taking the deposition of the potentially at-fault non-party or, at minimum, someone with knowledge of the actions of the potentially at-fault non-party. I cannot imagine being able to effectively present a comparative fault claim to the jury without some testimony (in person or by deposition) regarding the actions of the potentially at-fault non-party.

30. To be required to prove an affirmative allegation of fault without the opportunity to obtain testimony from anyone related to the potentially at-fault party is unfairly and unduly prejudicial to the presentation of the defense. As noted earlier in this affidavit, Tennessee law directs the jury to *compare* the fault of the defendants with non-parties. An anemic, cold-document-only presentation of the factual basis for the

[30] Notably, the PSC has taken the depositions of more than a dozen of the Tennessee Defendants' employees to build their case of liability. Despite this, they argue (apparently without recognizing the irony) that we do not need any depositions of NECC/MSM employees to build our case against NECC/MSM.

comparative fault of NECC, its owners, pharmacists, technicians, and the employees of its sales arm, MSM, will limit the degree of fault assigned by the jury to the principal entities at fault in this entire controversy. To be required to do so here would severely prejudice my clients.

Expert Testimony

31. We retained experts to defend our clients' decision to purchase from NECC and, separately, to evaluate the actions of (and likely criticize) NECC and its affiliates. The testimony of NECC/MSM employees is important to these expert reports.

32. At this point, the experts are forming opinions based solely on the documents, what we tell them, and the testimony of our witnesses. They do not have any information directly from someone who worked at NECC or MSM about the workings of NECC/MSM or explaining the documents.

33. If forced to disclose experts and present experts for depositions before the depositions of these NECC/MSM employees, it is likely that the reports will have to be supplemented after the depositions are taken. This comment is particularly applicable to the experts retained to criticize NECC. The depositions of the NECC/MSM employees will probably reveal information about the internal operations of NECC/MSM, including where, how, and by whom the medications were actually created and sterilized. I expect that our experts will comment directly on that testimony.

Comparative Fault of Other Parties

34. We also asserted as a defense the comparative fault of non-parties unaffiliated with NECC (*e.g.*, ARL, UniFirst, Liberty). The testimony of NECC/MSM will be essential to proving the fault of these other unaffiliated non-parties.

35. As an example, we need to establish NECC's expectations regarding ARL. Did NECC expect or rely upon ARL to handle all aspects of the independent sterility testing, including determining how many vials in each batch had to be tested to meet basic USP standards? Did NECC rely on ARL to determine which type of test to run on the samples? Did NECC actually know that ARL had a proprietary sterility test, specific to fungal organisms, which, if employed before shipment to the public in a sufficient number of vials, would have prevented this entire tragedy? Answers to these questions will be essential to the jury determining what, if any, fault to allocate to ARL for negligently handling the outside, independent testing of the medications.

36. Information from the NECC/MSM depositions will also bear on the fault of UniFirst (Did NECC complain to UniFirst that it was not properly cleaning the premises? Did UniFirst address the complaints?) and Liberty (Did NECC, as Liberty contends, provide all the specifications for Liberty to construct the cleanroom? Or, did NECC rely on Liberty to design and safely build the cleanroom?). This information will be essential for the jury in apportioning fault to UniFirst and Liberty.

Information from Depositions Relevant to Non-Comparative Fault Defenses

37. Information from the NECC/MSM depositions is relevant not only to comparative fault of non-parties; it is also directly relevant to other defenses. Examples of the relevance of the testimony to other defenses in the cases have been previously shared in numerous pleadings in this MDL,[31] and are touched on in the concurrent *Response to Motion of the United States for a Stay of Certain Depositions pending Resolution of Related Criminal Proceedings*. A few examples bear mention again.

[31] *See, e.g.*, Dkt. 1862 (p. 3-5); Dkt. 2191 (p. 9-12).

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38. We plan to defend the claim that our clients violated the standard of care by failing to perform the proper due diligence before purchasing from NECC in at least two (2) ways:

a. First, we intend to prove what we believe to be true based on our investigation to date: That, of the thousands of customers of NECC across this nation, virtually *none* did the level of due diligence that the Plaintiffs allege was the "standard of care." To do so, we must establish what due diligence most customers did before purchasing from NECC.[32]

b. Second, we intend to prove that, even had our clients done the due diligence the Plaintiffs contend was "standard" (*e.g.*, do a site visit of NECC before buying; perform a paper audit of NECC before buying), the due diligence would not have revealed anything to deter our clients from purchasing from NECC. We intend to establish with NECC and MSM what a site visit and "paper audit" of NECC in 2011 would have revealed. We likewise intend to establish that NECC/MSM's mode of operation was to assure customers that it followed all sterility standards,[33] and even represented to customers that NECC was registered with the FDA.

39. To defend the case on both (a) and (b), we must obtain testimony from NECC/MSM. Otherwise, we are left trying to establish both points based on an

[32] We have attempted to gain this information from NECC via a corporate witness (the Court denied this) and via requests for admission to the PSC (the PSC refused to answer these).

[33] We must also present evidence supporting the notion that it was reasonable for our clients to conclude NECC was just like any other manufacturer they dealt with. To do so, we need to establish that NECC made a concerted effort to operate like and hold itself out as a drug manufacturer. This requires, again, the testimony of NECC/MSM.

incomplete set of unauthenticated, unexplained documents with little inherent persuasive force.

* * * * * * *

40. In Tennessee, a tortfeasor is relieved of liability if an independent cause intervenes to produce a result that the negligent actor could not have reasonably foreseen.[34] If the intervening cause was sufficient to cause the injury, not reasonably foreseeable, and not a normal consequence of the negligent actor's conduct, the tortfeasor cannot be found liable.[35]

41. We intend to establish that the conduct of NECC/MSM was (1) an independent cause of the contamination and injury and (2) not reasonably foreseeable to our clients. To do so, we intend to identify the specific conduct that caused contamination of product made by NECC and develop facts to establish that the contamination was not reasonably foreseeable (and possibly criminal). These facts must be developed through depositions of NECC/MSM.[36]

Summary of Necessity of NECC/MSM Depositions

42. In my opinion, depositions of the former employees of NECC and MSM are essential to the effective defense of the claims against my clients. To require us to disclose experts, conduct expert discovery, and try the first civil case without the benefit of testimony from the NECC and MSM former employees would be unduly and unfairly prejudicial to our defense of the cases.

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[34] *Potter v. Ford Motor Co.*, 213 S.W.3d 264, 273 (Tenn. Ct. App. 2006).
[35] *Id.* at 273.
[36] The criminality of NECC/MSM's conduct will obviously be the subject of the criminal trial. The AUSA's office has told us in discussions about the *Motion to Stay* that the criminal trial will provide us with mounds of information that we do not have about NECC and its operations. If that is true, and the actions of the NECC insiders were indeed criminal acts (and unforeseeable), that will absolve our clients entirely from liability.

43. Trial of the first civil case on an incomplete factual record, and with the Tennessee Clinic Defendants required to present a central affirmative defense in the least convincing fashion, is neither just nor sensible. A verdict in that case would have little predictive value for the remainder of the Tennessee cases.

Conclusion

44. We intend no interference with the criminal process.

45. Our position, as set out in the *Response to Motion of the United States for a Stay of Certain Depositions pending Resolution of Related Criminal Proceedings*, is simple: We must have the depositions of the former employees of NECC and MSM prior to disclosing experts and making final preparations to try the first civil case.

C.J. Gideon, Jr.
(Counsel for Tennessee Clinic Defendants)

Sworn to and subscribed by me on this 28th day of September, 2015.

(Notary Public)

My Commission Expires: 07/03/17

LINDA DEBAUN
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
MY COMMISSION EXPIRES July 3, 2017

EXHIBIT A

IN THE CIRCUIT COURT OF DAVIDSON COUNTY, TENNESSEE

WAYNE A. REED, individually and as Husband and next of kin of decedent, DIANA E. REED,	)	
Plaintiff,	)	
v.	)	**NO. 13C417**
SAINT THOMAS OUTPATIENT NEUROSURGICAL CENTER, LLC, HOWELL ALLEN CLINIC, a Professional Corporation, SAINT THOMAS NETWORK, SAINT THOMAS HEALTH, and ST. THOMAS HOSPITAL	)	
Defendants.	)	

ANSWER OF THE DEFENDANTS, ST. THOMAS OUTPATIENT NEUROSURGICAL CENTER, LLC AND HOWELL ALLEN CLINIC, A PROFESSIONAL CORPORATION

For their Answer to the Complaint, the Defendants St. Thomas Outpatient Neurosurgical Center, LLC ("STOPNC") and Howell Allen Clinic, a Professional Corporation ("Howell Allen") (collectively, the "Defendants"), state as follows:

20. The Plaintiff's claims against the limited liability companies should be dismissed consistent with Tenn. Code Ann. § 48-217-101(a) as members, holders of financial interests, governors, managers, employees, or other agents of an LLC do not have personal obligations and are not liable personally for the acts, debts, liabilities, or obligations of the LLC. Additionally, pursuant § 48-217-101(e), failure of the LLC to observe the usual company formalities or requirements shall not be grounds for personal liability of members, governors, managers, employees, or other agents.

COMPARATIVE FAULT

NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin

1. The Defendants assert the doctrine of comparative fault against NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin who, individually, through employees and agents, and/or collectively, owed a duty to Ms. Reed and her healthcare providers to provide medication that was free from contamination and safe for its intended use.

2. NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin, individually, through employees and agents, and/or collectively, breached this duty, proximately causing the alleged injuries and damages, as further explained in the following paragraphs.

Contamination of MPA

3. The Defendants assert the doctrine of comparative fault against NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin, individually and collectively, for proximately causing the alleged injuries and damages by negligently or recklessly committing various acts or omissions including, but not limited to:

a. Contaminating the MPA that was eventually injected into Ms. Reed, allegedly causing her death;

b. Failing to adequately inspect and test the MPA prior to distribution to ensure that it was free from contamination and safe for its intended use; and

c. Failing to train and/or supervise the individuals responsible for compounding, inspecting, and/or testing the MPA to ensure that it was free from contamination and safe for its intended use.

Violation of Applicable Laws and Guidelines

4. The Defendants assert the doctrine of comparative fault against NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin, individually and collectively, for proximately causing the alleged injuries and damages by negligently or recklessly failing to comply with applicable state and federal laws after multiple warnings and inspections by the FDA and the MBP as described herein.

5. NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin violated state and federal laws including, but not limited to:

a. Failing to comply with good manufacturing practices as required by 21 U.S.C. § 351;

b. Failing to obtain new drug approval as required by 21 U.S.C. § 355;

c. Wholesaling drugs or medications without a license in violation of Mass. Gen. Laws ch. 112, § 36A;

d. Failing to comply with all USP guidelines as required by 247 C.M.R. 9.01(3);

e. Failing to comply with USP 797 as required by 247 C.M.R. 6.15(f);

f. Dispensing medication without a valid prescription as required by 247 C.M.R. 6.15(f);

g. Failing to report all errors relating to the preparation of medications inconsistent with USP 797 as required by 247 C.M.R. 6.15(6); and

h. Dispensing medication in a manner intended to circumvent the law in violation of 247 C.M.R. 9.01(2).

6. NECC and Barry Cadden violated Tennessee pharmaceutical laws and regulations including, but not limited to:

a. Violating Tenn. Code Ann. § 63-10-305 by:

i. Engaging in conduct prohibited or made unlawful by any of the provisions of parts 2-5 of that chapter or any other state or federal laws relating to drugs or the practice of pharmacy;

ii. Being guilty of dishonorable, immoral, unethical, or unprofessional conduct; and

iii. Failing to comply with duly promulgated rules of the Tennessee Board of Pharmacy ("TBP");

b. Violating Tenn. Comp. R. & Regs. No 1140-01-.08 by:

i. Failing to submit a copy of NECC's May 24, 2011 inspection report conducted by the MBP to the TBP;

ii. Failing to maintain records of prescription orders dispensed to persons residing in Tennessee;

iii. Failing to make readily available any records of prescription orders prepared and dispensed to persons residing in Tennessee;

iv. Failing to ensure that each of the 2,520 vials of MPA dispensed in Tennessee by NECC were only dispensed after NECC received patient-specific prescriptions for each of those vials; and

v. Failing to comply with the requirements for patient counseling, patient profiling, drug regimen review, and pharmaceutical care as set forth in Tenn. Comp. R. & Regs. No. 1140-03-.01.

c. Violating Tenn. Comp. R. & Regs. No. 1140-03-.03 by failing to ensure that each of the 2,520 vials of MPA dispensed in Tennessee were only dispensed after NECC received patient-specific prescriptions for each of those vials; and

d. Violating Tenn. Comp. R. & Regs. No. 1140-07-.02 by failing to ensure that each of the 2,520 vials of MPA dispensed in Tennessee were free from contamination and safe for their intended use.

7. NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin violated USP guidelines by:

a. Failing to submit adequate samples for sterility and endotoxin testing;

b. Filling only enough vials for sterility testing and leaving the remaining medication in a bulk container until sterility results were obtained;

c. Distributing compounded medication prior to receiving the results of sterility testing;

d. Failing to properly sterilize autoclaves;

e. Failing to properly validate autoclaves prior to use;

f. Failing to properly test autoclaves prior to use;

g. Failing to properly sterilize batches of MPA;

h. Failing to ensure sterility and cleanliness of the clean room used to manufacture MPA;

i. Manufacturing MPA where residual powder existed on laminar hoods creating a high risk of contamination of the drug product;

j. Failing to clean or replace the clean room "tacky mats;"

k. Compounding sterile preparations with a leaky boiler in an adjacent room creating a high risk of contamination of the drug product;

l. Placing the clean room HVAC unit near a recycling facility; and

m. Failing to maintain continuous ventilation of clean rooms.

Products Liability and Breach of Warranties

8. The Defendants assert the doctrine of comparative fault against NECC, Barry Cadden, Lisa Cadden, and/or Glenn Chin for proximately causing the alleged injuries and damages by violating the Tennessee Products Liability Act of 1978 codified at Tenn. Code Ann. § 29-28-101, *et seq.*

9. NECC, Barry Cadden, Lisa Cadden, and/or Glenn Chin acted as a manufacturer as defined by Tenn. Code Ann. § 29-28-102 by compounding the MPA.

10. When the MPA left the control of NECC, Barry Cadden, Lisa Cadden, and/or Glenn Chin, it was in a defective condition as defined by Tenn. Code Ann. § 29-28-102 because it was contaminated and unsafe for injection into patients like Ms. Reed.

11. Contamination of the MPA proximately caused all injuries and damages alleged.

12. As a result, NECC, Barry Cadden, Lisa Cadden, and/or Glenn Chin are strictly liable for all injuries and damages alleged.

13. NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin, individually and collectively, proximately caused the alleged injuries and damages by negligently or recklessly breaching various express and implied warranties codified at Tenn. Code Ann. §§ 47-2-313 to -315, including the warranties of fitness for a particular purpose and merchantability.

Misleading Healthcare Providers and Regulatory Authorities

14. The Defendants assert the doctrine of comparative fault against NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin, individually and collectively, for proximately causing the alleged injuries and damages by negligently or recklessly committing various acts or omissions including, but not limited to:

a. Misrepresenting to healthcare providers that NECC's manufacturing processes and facilities were in compliance with USP guidelines;

b. Manufacturing and distributing MPA to healthcare providers in bulk for general use rather than in response to individual patient-specific prescriptions; and

c. Misrepresenting to healthcare providers, the FDA, the MBP, and the TBP that NECC was operating as a compounding pharmacy rather than a manufacturer.

15. On January 28, 2005, in a sworn statement on his initial application for a Tennessee pharmacy license, Barry Cadden answered "No" to the following question:

> Are there any charges involving moral turpitude or violation of pharmacy, or any other laws pending against you? Explain such charges or violations in detail; even to reporting minor infractions of pharmacy, liquor or narcotic laws [sic] regulations; include dates.

16. At the time, Barry Cadden had, at least, three pending, but nonpublic complaints before the Massachusetts Board of Pharmacy.

United States Food and Drug Administration

17. The Defendants assert the doctrine of comparative fault against the United States Food and Drug Administration ("FDA"), which owed a duty to Ms. Reed as well as her healthcare providers to ensure that MPA manufactured, sold, and distributed by NECC was sterile and safe for its intended use pursuant to the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 301, *et. seq.*

18. The FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

19. The Defendants assert the doctrine of comparative fault against the FDA for proximately causing the alleged injuries and damages by negligently or recklessly failing to take action against NECC even though the FDA had authority to do so, as asserted in its October 31, 2008 letter to NECC, which was not publicly available prior to the outbreak of fungal meningitis, and only became available after the state and federal agencies with the responsibility to oversee NECC were subjected to appropriate scrutiny.

20. The FDA breached its duty, proximately causing all injuries and damages alleged, as further explained herein.

Failure to Make Information Publicly Available

21. The FDA proximately caused the alleged injuries and damages by negligently or recklessly failing to make publicly available all complaints, inspection reports, and information gathered during its serial investigations of NECC, described herein.

22. The FDA failed to notify the Tennessee Board of Pharmacy ("TBP") and other state pharmacy boards of the potential threat to public health caused by NECC's non-public track record of regulatory non-compliance with state and federal law, and unsatisfactory results from on-site surveys.

23. To and including the time when STOPNC ordered and received shipment of the contaminated MPA from NECC, the only piece of information readily available to the public regarding NECC's history with regulatory agencies was the FDA's 2006 Warning Letter to NECC.

24. However, the Warning Letter does not mention any problems with MPA or any other steroids compounded by NECC, and it does not mention any reports of problems with the sterility of any medications compounded at NECC.

25. No other information regarding NECC's history with the FDA was readily and publicly available up to and including the time when STOPNC ordered and received shipment of the contaminated MPA from NECC.

26. On December 4, 2006, the FDA failed to issue a Public Health Alert to healthcare providers, warning them of the problems at NECC identified in the Warning Letter issued the same day.

27. To and including the time when STOPNC ordered and received shipment of the contaminated MPA from NECC, the FDA, MPB, and NECC were aware of the serious nature and extent of the repeated problems at NECC.

28. The Defendants were unaware of the serious nature and extent of NECC's problems.

Multiple Complaints and Inspections without Disciplinary Action

29. Despite the fact that the FDA's budget more than doubled during the time in question from $1.55 billion in 2002 to $3.83 billion in 2012[2], the FDA proximately caused the alleged injuries and damages by negligently or recklessly failing, to discipline or take action against NECC after becoming aware of NECC's failure to comply with applicable state and federal laws and manufacturing guidelines, including, but not limited to, the following incidents, which were not publicly reported prior to the outbreak of fungal meningitis, and only became public after the state and federal agencies with the responsibility to oversee NECC were subjected to appropriate scrutiny:

a. In April 2002, after receiving two MedWatch reports of adverse events following injections of betamethasone compounded by NECC, the FDA inspected NECC and observed problems with sterility.

b. In July 2002, after receiving three additional MedWatch reports of two patients developing bacterial meningitis at a New York hospital following injections of MPA compounded by NECC, FDA investigators determined that NECC's sterility testing procedures were not in compliance with USP guidelines for sample size in relation to lot quantities, and the FDA testing found contamination in four (4) of the 14 vials tested.

[2] The 2012 budget is an estimate provided by the Department of Health and Human Services to Congress in its 2013 budget justification. The actual 2012 budget is not yet available.

c. In August 2002, after receiving a report that patients developed meningitis following epidural steroid injections of MPA compounded by NECC, the FDA found bacterial contamination in five (5) of the 16 vials tested and concluded that NECC had sterility and potency issues with MPA and betamethasone.

d. On February 5, 2003, during a joint meeting with the MBP to review NECC's inspection history and ostensibly to formulate a joint state-federal strategy for achieving safe compounding practices at the company, the FDA emphasized to the MBP the serious threat to public health posed by NECC's sterile compounding practices absent improvement.

e. Following the meeting, the FDA's own investigators recommended that NECC be enjoined from compounding medication for failing to comply with good manufacturing practices in the event that the MBP failed to take action against NECC.

f. On April 27, 2004, the FDA and the MBP conducted a joint inspection of NECC after receiving two new complaints against NECC:

i. First, a Wisconsin pharmacist reported that NECC's representative told the pharmacist that NECC needed a prescription for extra strength triple anesthetic cream, but the representative stated that the pharmacist could use the name of a staff member. NECC's representative also stated that another healthcare provider used a nurse's name.

ii. Second, an Iowa pharmacist reported that NECC was advertising compounded prescription products for use by multiple patients with a single prescription.

g. On September 23, 2004, the FDA and the MBP conducted a joint inspection of NECC after receiving a complaint that NECC was compounding Trypan Blue Dye for use as a capillary stain during ophthalmic procedures, which was not an approved use.

i. During the inspection, Barry Cadden, an owner, and the pharmacist in charge at NECC, told investigators that NECC did not compound Trypan Blue until they received a prescription.

ii. But soon thereafter, investigators discovered a drawer with 189 vials of Trypan Blue, with no corresponding prescriptions.

h. In November 2004, Barry Cadden admitted in a letter to the MBP, which was later shared with the FDA, that NECC had filled prescriptions for Trypan Blue using invalid patient names.

i. In May 2011, the FDA's district office in Denver, Colorado notified the New England District Office of the FDA that NECC had violated a Cease and Desist Letter issued by the Colorado Board of Pharmacy that prohibited NECC from distributing drugs in Colorado without receiving patient-specific prescriptions.

j. The FDA took no meaningful, substantive action.

2006 Warning Letter

30. The Defendants assert the doctrine of comparative fault against the FDA for proximately causing the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC after issuing a Warning Letter to NECC on December 4, 2006, detailing numerous problems at NECC, including:

a. Compounding drugs without patient-specific prescriptions;

b. Compounding copies of commercially-available drugs;

c. Selling misbranded compounded drugs; and

d. Failing to correct problems with storage and sterility.

31. On January 5, 2007, NECC responded to the FDA's Warning Letter, but NECC's response letter was not publicly available up to and including the time when STOPNC ordered and received shipment of the contaminated MPA from NECC.

32. On October 31, 2008, the FDA replied to NECC's response in a third letter that was not publicly available up to and including the time when STOPNC ordered and received shipment of the contaminated MPA from NECC.

33. The FDA, based on available information, failed to perform the follow-up inspection promised in its October 31, 2008 letter.

34. The FDA failed to take any readily apparent action against NECC after sending the December 4, 2006 Warning Letter, even though the Warning Letter threatened "additional regulatory action without further notice."

Failure to Comply with the FDA Compliance Policy Guidance on Pharmacy Compounding

35. The Defendants assert the doctrine of comparative fault against the FDA for proximately causing the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC even though the FDA knew that NECC had violated the FDA's Compliance Policy Guidance on Pharmacy Compounding in, at least, the following ways:

a. Compounding drugs in anticipation of receiving prescriptions (as evidenced by multiple complaints from state pharmacy boards as well as the FDA's own inspections);

b. Using commercial scale compounding equipment for compounding drug products (*e.g.*, ExactaMix EM2400 compounders);

c. Compounding drug products that were commercially available in the marketplace or that were essentially copies of commercially available FDA-approved drug products (as evidenced by a 2004 patent infringement lawsuit filed by Dusa Pharmaceuticals against NECC for copying a commercially available FDA-approved drug manufactured by Dusa Pharmaceuticals); and

d. Failing to operate in conformance with applicable state law regarding the practice of pharmacy (as evidenced by multiple complaints from state pharmacy boards as well as the FDA's own inspections).

Failure to Inspect Analytical Research Laboratories, Inc.

36. The Defendants assert the doctrine of comparative fault against the FDA for proximately causing the alleged injuries and damages by negligently or recklessly failing to adequately inspect Analytical Research Laboratories, Inc. pursuant to the authority granted by 21 U.S.C. § 360(h), prior to November 8, 2012, when the FDA discovered multiple violations related to the testing of NECC medications including:

a. Failing to comply with USP 71 when performing sterility and/or fungal testing on NECC products by:

i. Failing to maintain adequate documentation demonstrating the performance of Method Suitability Testing on all new NECC products tested; and

ii. Failing to ensure that NECC submitted the required number of vials for testing.

b. Failing to comply with USP 85 in performing endotoxin testing by:

i. Failing to calculate the Maximum Valid Dilution using the formula in USP 85; and

ii. Failing to ensure that each client provided the dosing information required to calculate the Maximum Valid Dilution using the formula in USP 85.

c. Failing to maintain documentation demonstrating validation of all analytical methods for testing the potency of NECC's products; and

d. Failing to conduct further investigation following 13 endotoxin testing failures that occurred between October 2010 and October 2012.

Massachusetts Board of Pharmacy

37. The Defendants assert the doctrine of comparative fault against the Massachusetts Board of Pharmacy ("MBP") which owed a duty to Ms. Reed as well as her healthcare providers to ensure that NECC compounded medication free from contamination and operated in compliance with applicable Massachusetts pharmaceutical laws pursuant to Mass. Gen. Laws ch. 112, § 32.

38. The MPB breached this duty, proximately causing all injuries and damages alleged, as further explained below.

Failure to Make Information Publicly Available

39. The MBP proximately caused the alleged injuries and damages by negligently or recklessly failing to make publicly available all complaints, inspection reports, and information gathered during investigations regarding NECC, described herein.

40. Based on available information, the MBP failed to notify the Tennessee Board of Pharmacy ("TBP") and other state pharmacy boards of the potential threat to public health caused by NECC's non-public track record of regulatory non-compliance with state and federal law, and unsatisfactory results from on-site surveys.

41. To and including the time when STOPNC ordered and received shipment of the contaminated MPA from NECC, the MBP, the FDA, and NECC were aware of the serious nature and extent of the repeated problems at NECC.

42. None of the information regarding the MBP's serial inspections and investigations of NECC was readily and publicly available up to and including the time when STOPNC ordered and received shipment of the contaminated MPA.

43. The Defendants were unaware of the serious nature and extent of NECC's problems.

Multiple Complaints and Inspections without Disciplinary Action

44. The MBP proximately caused the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC after becoming aware of NECC's failure to comply with applicable state and federal laws and manufacturing guidelines, including, but not limited to, the following incidents, which were not publicly reported prior to the outbreak of fungal meningitis, and only became public after the state and federal agencies with the responsibility to oversee NECC were subjected to appropriate scrutiny:

a. In 1999, Barry Cadden violated MBP regulations by providing a practitioner with blank prescription pads referring to NECC.

b. In 2001, the Idaho Board of Pharmacy reported to the MBP that NECC was soliciting business for drug products which should have been discontinued by the manufacturer.

c. In 2002, the Nevada Board of Pharmacy reported to the MBP that NECC was selling non FDA-approved products to physicians in Nevada.

d. Between 2002 and 2004, the MBP received complaints from the boards of pharmacy for Texas, South Dakota, Iowa, and Wisconsin, reporting that NECC was illegally soliciting out-of-state prescriptions for office use.

e. In March 2002, the MBP and the FDA conducted a joint inspection of NECC following the FDA's receipt of two MedWatch reports of adverse events resulting from injections of betamethasone compounded at NECC.

i. During the joint investigation, the MBP apparently failed to inform the FDA of the MBP's past inspections of NECC.

ii. The MBP also apparently failed to disclose positive endotoxin testing results for the implicated lot of betamethasone to the FDA.

iii. The FDA expressed serious concerns regarding the sterility of NECC's betamethasone compounding and NECC's recordkeeping in the 483 report issued by the FDA following the investigation.

f. In July 2002, after receiving three additional MedWatch reports of two patients developing bacterial meningitis at a New York hospital following injections of MPA compounded at NECC, FDA investigators determined that NECC's sterility testing procedures were not in compliance with USP guidelines for sample size in relation to lot quantities, and FDA testing found contamination in four (4) of the 14 vials tested.

g. In August 2002, after receiving a report that patients developed meningitis following epidural steroid injections of MPA compounded by NECC, the FDA found bacterial contamination in five (5) of the 16 vials tested and concluded that NECC had sterility and potency issues with MPA and betamethasone.

h. However, on February 5, 2003, during a meeting between the FDA and the MBP, the MPB agreed that it, rather than the FDA, would either require compliance from NECC or take action against NECC.

i. At the February 5, 2003 meeting, the FDA recommended that NECC be prohibited from manufacturing until it demonstrated the ability to make product reproducibly and dependably.

ii. Also at the February 5, 2003 meeting, the FDA warned of the potential for serious public health consequences if NECC's sterile compounding practices were not improved.

iii. The MBP did not discernibly respond to these recommendations and warnings.

i. After the February 5, 2003 meeting, the MBP delayed more than a year before proposing a consent agreement to NECC on September 21, 2004.

i. However, NECC refused to enter into the agreement. The MBP failed to proceed to a formal hearing as provided for in the consent agreement in the event of a refusal by NECC to accept the proposal.

ii. On April 27, 2004, the FDA and the MBP conducted another joint inspection of NECC after receiving two new complaints against NECC:

1. First, a Wisconsin pharmacist reported that NECC's representative told the pharmacist that NECC needed a prescription for extra strength triple anesthetic cream, but the representative stated that the pharmacist could use the name of a staff member. The representative also stated that another healthcare provider used a nurse's name.

2. Second, an Iowa pharmacist reported that NECC was advertising compounded prescription products for use by multiple patients with a single prescription.

j. On September 23, 2004, the FDA and the MBP conducted a joint inspection of NECC after receiving a complaint that NECC was compounding Trypan Blue Dye for use as a capillary stain during ophthalmic procedures, which was not an approved use.

i. During the inspection, Barry Cadden told investigators that NECC did not compound Trypan Blue until they received a prescription.

ii. But soon thereafter, investigators discovered a drawer with 189 vials of Trypan Blue, with no corresponding prescriptions.

iii. In November 2004, Barry Cadden admitted to the MBP that NECC had filled prescriptions for Trypan Blue using invalid patient names.

k. On January 30, 2006, the MBP received an initial audit from Pharmacy Support, Inc., an independent evaluator, reporting that NECC was not in substantial compliance with USP 795 or USP 797. The audit noted the following deficiencies:

i. Documentation practices were inadequate;

ii. Written procedures were admittedly not followed routinely;

iii. Procedures were not in strict accordance with USP standards;

iv. End product testing was often performed on stock solutions and not the end product as required; and

v. Validation of sterilization cycles and media fills was inadequate.

l. On April 7, 2006, the MBP received Pharmacy Support, Inc.'s final report which concluded that NECC needed to redesign Clean Room 1 in order to achieve compliance with USP 795 and USP 797.

m. On December 4, 2006, the FDA issued a Warning Letter to NECC detailing numerous problems at NECC including:

i. Compounding drugs without patient-specific prescriptions;

ii. Compounding copies of commercially-available drugs;

iii. Selling misbranded compounded drugs; and

iv. Having problems with storage and sterility.

Formal Complaints Filed in 2003

45. The Defendants assert the doctrine of comparative fault against the MBP for proximately causing the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC in February 2003 after issuing formal complaints against NECC identifying serious problems including:

a. Failing to follow sterility guidelines and procedures;

b. Failing to follow record-keeping requirements;

c. Failing to follow batch record-keeping requirements;

d. Failing to provide certificates of analysis;

e. Failing to provide proof of sterility testing;

f. Failing to provide endotoxin test results;

g. Failing to provide batch numbers; and

h. Failing to provide prescriptions upon request.

46. However, the MBP failed to pursue any disciplinary action against NECC that would actually correct these problems even though the MBP investigator who performed a follow-up inspection in late February 2003 recommended a formal reprimand.

2011 Report from the Colorado Board of Pharmacy

47. The Defendants assert the doctrine of comparative fault against the MPB for proximately causing the alleged injuries and damages by negligently or recklessly failing to shut down, or even inspect NECC, after receiving notice from the Colorado Board of Pharmacy on July 26, 2012 that NECC had violated a Cease and Desist Order issued by the Colorado Board of Pharmacy prohibiting NECC from selling medications in Colorado prior to receiving patient-specific prescriptions.

48. If the MBP had promptly acted on the July 26, 2012 report, it would have discovered the dismal sterility conditions at NECC and required a recall of all NECC medications before Ms. Reed had her first injection on August 21, 2012.

49. In November 2012, James Coffey, the Director of the MBP, was terminated for failing to investigate NECC following receipt of the report from the State of Colorado, and for covering up the MBP's receipt of the July 26, 2012 report from the Colorado Board of Pharmacy.

Tennessee Board of Pharmacy

50. The Plaintiff has alleged that the Defendants had a duty to inspect NECC's facilities prior to purchasing medications, had a duty to determine NECC's history of recalling medications, had a duty to investigate NECC's history with the FDA and MBP, and otherwise had a duty to perform due diligence in investigating and selecting NECC.

51. Based on the allegations of the Complaint, the Defendants assert comparative fault against the Tennessee Board of Pharmacy ("TBP"), which had the explicit legal authority to inspect NECC which was doing business in Tennessee as a licensee of the TBP.

52. The Defendants assert the doctrine of comparative fault against the TBP in order to avoid waiver of the issue under Rule 8.03 of the Tennessee Rules of Civil Procedure and the Tennessee Supreme Court's decision in *George v. Alexander*, 931 S.W.2d 517, 520-21 (Tenn. 1996).

53. If it is established that the TBP breached its duty by: failing to timely investigate and bring charges against NECC for the violations outlined herein, failing to inquire of the MBP regarding actions against NECC, or failing to inspect NECC's facility, the Defendants assert fault against the TBP.

54. The Plaintiff has alleged the Defendants, as private healthcare providers, had the duty to fully investigate and inspect NECC before doing business with it in Tennessee. Based on these allegations, the Defendants plead the fault of the TBP and assert that any findings of fault against the Defendants for failure to act reasonably in choosing NECC be compared against any fault found on the part of the TBP for failing to comply with its duty to reasonably evaluate and license NECC.

Tennessee Department of Health

55. Likewise, based on specific allegations in the Complaint, the Defendants are required to assert comparative fault against the Tennessee Department of Health ("TDH") for any claims arising from an alleged failure to notify Ms. Reed of her potential exposure to contaminated MPA prior to her hospitalization on September 23, 2012.

56. The Defendants assert the doctrine of comparative fault against the TDH in order to avoid waiver of the issue under Rule 8.03 of the Tennessee Rules of Civil Procedure and the Tennessee Supreme Court's decision in *George v. Alexander*, 931 S.W.2d 517, 520-21 (Tenn. 1996).

57. The Defendants allege that the TDH's actions were a cause-in-fact or a substantial factor in causing the Plaintiff's alleged injuries arising from the alleged failure to warn.

58. From the time STOPNC learned of potential exposure, it worked closely with the TDH to respond appropriately, particularly in the first days of this complicated and fluid outbreak. STOPNC relied on the TDH for advice on contacting patients and responded to the outbreak both consistent with and in tandem with the TDH, and within the acceptable standards of professional practice.

59. STOPNC promptly complied with all instructions from the TDH and CDC regarding contacting patients, including an initial directive from the TDH not to mention meningitis.

60. STOPNC relied upon and promptly complied with all directives and guidance received from the TDH related to this fungal meningitis outbreak.

61. If it is established that the TDH did not recommend appropriate notification of patients, the Defendants are constrained to assert comparative fault against the TDH.

Medical Sales Management, John Notarianni, and Mario Giamei

62. The Defendants assert the doctrine of comparative fault against Medical Sales Management, John Notarianni, and Mario Giamei who, individually and collectively (and acting as employees/agents of NECC and/or Medical Sales Management), owed a duty to Ms. Reed and her healthcare providers to provide truthful information regarding the safety and sterility of NECC's products and NECC's compliance with applicable state and federal law and USP guidelines.

63. Medical Sales Management, John Notarianni, and Mario Giamei breached this duty, proximately causing all injuries and damages alleged, as further explained in the following paragraphs.

64. The Defendants assert the doctrine of comparative fault against Medical Sales Management, John Notarianni, and Mario Giamei, individually and collectively, for proximately causing the alleged injuries and damages by negligently or recklessly committing various acts or omissions including, but not limited to:

a. Misrepresenting to healthcare providers that NECC's products were safe and sterile;

b. Misrepresenting to healthcare providers that NECC's manufacturing facilities and processes complied with USP guidelines;

c. Assisting or causing NECC to circumvent the requirement that NECC only compound and distribute medications after receiving valid patient-specific prescriptions; and

d. Failing to adequately train and/or supervise John Notarianni and/or Mario Giamei in the advertising, selling, and/or distribution of NECC's medications.

Analytical Research Laboratories, Inc.

65. The Defendants assert the doctrine of comparative fault against Analytical Research Laboratories, Inc. which owed a duty to Ms. Reed and her healthcare providers to properly test medications submitted by NECC that would eventually be administered to Ms. Reed by her healthcare providers.

66. Analytical Research Laboratories, Inc. breached this duty, proximately causing all injuries and damages alleged, as explained in the following paragraphs.

67. The Defendants assert the doctrine of comparative fault against Analytical Research Laboratories, Inc. for proximately causing the alleged injuries and damages by negligently or recklessly committing various acts or omissions including, but not limited to:

a. Failing to discover contamination in the three contaminated lots of MPA from NECC, lots 05212012@68, 06292012@26, and 08102012@51;

b. Failing to comply with guidelines governing the testing of NECC's medications including, but not limited to:

i. Failing to comply with USP 71 when performing sterility and/or fungal testing on NECC products by:

1. Failing to maintain adequate documentation demonstrating the performance of Method Suitability Testing on all new NECC products tested; and

2. Failing to ensure that NECC submitted the required number of vials for testing.

ii. Failing to comply with USP 85 when performing endotoxin testing by:

1. Failing to calculate the Maximum Valid Dilution using the formula in USP 85; and

2. Failing to ensure that each client provided the dosing information required to calculate the Maximum Valid Dilution using the formula in USP 85.

iii. Failing to maintain documentation demonstrating validation of all analytical methods for testing the potency of NECC's products; and

iv. Failing to conduct further investigation following 13 endotoxin testing failures that occurred between October 2010 and October 2012.

UniClean

68. Based upon public information, NECC has notified UniClean Clean Room Services, which provided cleaning services for NECC, that it potentially is at fault for the contamination. As such, the Defendants assert the doctrine of comparative fault against UniClean Clean Room Service for failing to act consistent with its duty of care in cleaning the premises at NECC.

69. UniClean Clean Room Services breached this duty, proximately causing all injuries or damages alleged, as further explained in the following paragraphs.

70. The Defendants assert the doctrine of comparative fault against UniClean Clean Room Services for proximately causing the alleged injuries and damages by negligently or recklessly failing to clean NECC's clean rooms adequately enough during monthly cleanings to prevent contamination during the compounding of MPA.

Additional Parties Known and Unknown

71. The Defendants further rely upon the doctrine of comparative fault, to the extent that the discovery or proof in this cause should reveal that the direct and proximate cause, or a contributing cause, of any injury or damage to the Plaintiff was any act or omission by any person or entity which is a party to this litigation, as well as any person or entity not a party to this litigation. The Defendants reserve the right to amend their answer to assert specific conduct of parties to this action or other persons, as the facts become more fully known through discovery.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served on the following via U.S. mail, postage pre-paid, on this 1st day of March, 2013:

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